510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k061107

B. Purpose for Submission:
New 510(k)

C. Measurand:
Glucose, Sodium, Potassium, Chloride

D. Type of Test:
Quantitative Glucose hexokinase (Glucose)
Quantitative Ion Selective Electrodes (Na^+, K^+, Cl^-)

E. Applicant:
Thermo Electron Oy

F. Proprietary and Established Names:
DPC T60i KUSTI, Model 984248; Dpc T60i, Model 984247

G. Regulatory Information:

1. Regulation section:

21 CFR §	862.1345	Glucose test system.	II
21 CFR §	862.1170	Chloride test system.	II
21 CFR §	862.1600	Potassium test system.	II
21 CFR §	862.1665	Sodium test system.	II
21 CFR §	862.1150	Calibrator.	II
21 CFR §	862.1660	Quality control material (assayed and unassayed).	I, reserved
21 CFR §	862.2160	Discrete Photometric Chemistry Analyzer for Clinical Use	I

2. Classification:
See regulation section above

3. Product code:
CFR Hexokinase, Glucose
CGZ Electrode, Ion-Specific, Chloride
CEM Electrode, Ion Specific, Potassium
JGS Electrode, Ion Specific, Sodium
JIX Calibrator, Multi-Analyte Mixture
JJY Multi-Analyte Controls, All Kinds (Assayed And Unassayed)
JJE Analyzer, Chemistry (Photometric, Discrete), For Clinical Use

4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indications for use below

2. Indication(s) for use:
The DPC T60i and DPC T60i KUSTI Clinical Chemistry Analyzers are fully automated random access analyzers for in-vitro diagnostic use with clinical laboratory assays validated for use on these instrument platforms, including an

ISE unit with Na+, K+ and Cl- electrodes.

The DPC T60 Glucose (HK) test system with associated Calibrators and Controls is intended for quantitative in-vitro diagnostic determination of glucose in serum or plasma using the DPC T60i and DPC T60i KUSTI Clinical Chemistry Analyzers. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The DPC ISE Micro Volume Chloride, Potassium and Sodium Electrodes with associated Calibrators are intended for quantitative in-vitro diagnostic determination of Chloride, Potassium and Sodium in serum or plasma using the DPC T60i and DPC T60i KUSTI Clinical Chemistry Analyzers.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.

3. Special conditions for use statement(s):
   Prescription use
4. Special instrument requirements:
   DPC T60i and DPC T60i KUSTI Clinical Chemistry Analyzers

I. Device Description:

The DPC T60i is a random access discrete photometric and direct potentiometric analyzer, capable of performing 45 photometric tests and up to 5 potentiometric tests on 90 samples at a time.

The analyzer has the option for 2 sample modes; a manual load on sample disk and an automated load (KUSTI). The manual mode is where sample tubes and/or cups are manually loaded into a sample disk. The sample disk has an integrated barcode reader which allows cup/tube recognition. The barcode reader can read the following codes: code 128, code 39, USS Codabar, interleaved 2 of 5. The KUSTI option mode is where samples are automatically routed to bypass the sample module and are dispensed to a disposable KUSTI segment in the analyzer. Both samples types are dispensed by the same ISE dispenser and photometric dispenser.

Reaction cells are discrete disposable (single use) multicell cuvettes with 12 reaction measurement cells in a row. On-board capacity of 175 multicell cuvettes (equal to 2100 reaction cells), with continuous loading capability, typically 4 hours run time.

The quality of the reaction cells is checked at the start of the routine work automatically. The measurements are performed at 37ºC.

Reagents are liquid. The reagents bottles are placed on the reagent disk, which holds 45 positions. The reagent disk is cooled to 4 - 8ºC.

The operating system works with Windows ® XP. The user interface software is graphical. The data input can be done online or by touch screen or mouse or keyboard.

Methods:

The Glucose (HK) test system uses two reagents. Reagent A (buffer) contains 100 mmol/l Tris buffer (pH7.8) 2.1 mmol/l ATP, 2.1 mmol/l NAD, 4 mmol/l Mg^{2+} and <0.1% NaN_3. Reagent B (Enzyme) contains 4 mmol/l Mg^{2+}, >7.5 kU/L Hexokiniase, >7.5 kU/L G-6-P-DH and <0.1% NaN_3.

The Sodium, Potassium, and Chloride Micro Volume Electrode test system is comprised of ion selective electrodes for each ion Na, K, and Cl and a reference electrode.

sCal calibrator is intended for in vitro diagnostic use on T60 analyzer as a multicalibrator for quantitative measurements using methods defined by Thermo Electron Oy.

Nortrol and Abtrol Multi-analyte Controls, are intended for in vitro diagnostic use for quantitative testing on T60 analyzer. Nortrol is a control serum to monitor trueness and precision of the analytes listed in the separate Nortrol value sheet. The given values are valid for T60 Clinical Chemistry Analyzers using methods defined by Thermo Electron Oy. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Analyzers using methods defined by Thermo Electron Oy.

The ISE Calibrator 1 and 2&3 are intended for calibration of ion selective electrodes for quantitative measurements of potassium, sodium and chloride in human serum or plasma.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer Corporation, model Bayer ADVIA 1650 Chemistry System
   Bayer Corporation items:
   Bayer Advia 1650 Chemistry System Glucose
   Bayer Advia 1650 Chemistry System Chloride (Cl)
   Bayer Advia 1650 Chemistry System Potassium (K)
   Bayer Advia 1650 Chemistry System Sodium (Na)
   Bayer Advia 1650 Chemistry System Calibrators and Control

2. Predicate 510(k) number(s):
   k991576, k042015, k991575
3. Comparison with predicate:

Similarities

Attribute	Device	Predicate
Reagents	Same	Same
Analyzer • Discrete Photometric Analyzer • Software Driven • For clinical laboratory professionals • Automated dilutions • Sample reruns	 Same Same Same Same Same	 Same Same Same Same Same

Differences

Attribute	Device	Predicate
Reagents Testing Process • Clot detection • ISE testing	 No Direct	 Yes Indirect
Analyzer	DPC T60i KUSTI	Bayer ADVIA 1650 Chemistry System

K. Standard/Guidance Document Referenced (if applicable):

CLSI - Evaluation of Precision Performance of Clinical Chemistry Devices - EP05-A2
CLSI - Evaluation of the Linearity of Quantitative Analytical Methods - EP06-A
CLSI - Interference Testing in Clinical Chemistry - EP07-A2
CLSI - Method Comparison and Bias Estimation Using Patient Samples - EP09-A2

L. Test Principle:

Glucose Hexokinase method
Sodium, Potassium and Chloride Electrolyte measurements are performed directly with ion selective electrodes.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:
   Precision was performed using CLSI (former NCCLS) Document EP5-A2 as a guideline. The results are presented below.

	Assay	Mean	Total		Between run		Within run	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
I	Gluc(HK)	77 mg/dl	1.2	1.5	0.5	0.7	0.4	0.5
II	Gluc(HK)	265 mg/dl	3.5	1.3	1.2	0.5	1.4	0.5

I	ISE Cl^-	80.3 mmol/l	1.14	1.4	0.35	0.4	0.35	0.4
II	ISE Cl^-	109.9 mmol/l	0.83	0.8	0.33	0.3	0.35	0.3
I	ISE K^+	4.4 mmol/l	0.05	1.2	0.03	0.6	0.02	0.4
II	ISE K^+	5.9 mmol/l	0.08	1.3	0.03	0.4	0.03	0.5
I	ISE Na^+	128 mmol/l	1.0	0.7	0.4	0.3	0.3	0.3
II	ISE Na^+	145 mmol/l	0.9	0.6	0.2	0.2	0.3	0.2

b. *Linearity/assay reportable range:*
Linearity studies were performed using CLSI EP6-A as a guideline.

Glucose – measuring range is 5-720 mg/dl based on a dilution series with-in the claimed range. The assay recovered +/- 3mg/ml or +/- 5% from expected values.

Potassium – measuring range is 2.0-10.0 mmol/l based on a dilution series with-in the claimed range. The assay recovered +/- 0.25 mmol/l from expected values.

Sodium – measuring range is 100-200 mmol/l based on a dilution series with-in the claimed range. The assay recovered +/- 2.0 mmol/l or +/- 2.5% from expected values.

Chloride – measuring range is 55-150 mmol/l based on a dilution series with-in the claimed range. The assay recovered +/- 2.0 mmol/l or +/- 2.5% from expected values.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
sCal target values are determined using assay specific methods on the DPC T60 and other Thermo analyzer models. The target value is the median of all values obtained and traceable to a reference material. Glucose is traceable to NIST SRM 965.

Stability studies have been performed:
Open vial at 2-8 C 7 days
Shelf life 2-8 C 3 years

The target values of the Nortrol and Abtrol are control solutions are determined using assay specific methods on the DPC T60 and other Thermo analyzer models (calibrated by the sCal calibrator). The target value is the median of all values obtained.

Stability studies have been performed:
Open vial at 2-8 C 7 days
Reconstituted and -20 C 30 days

The ISE Calibrator are gravimetrically prepared using purity grade chemicals and purified laboratory water. The levels of the ISE calibrators are verified to

an in house reference. Value for sodium and chloride are traceable to NIST 919 and values for potassium are traceable to NIST 918.

Real time studies are used to determine shelf life and onboard stability.
Shelf life 2-30 C 20 months
Onboard 2-30 C 18 weeks

d. Detection limit:
Glucose Analytical sensitivity 2.0 mg/dl determined by 24 replicates of saline in a single run and calculated as 3 SD above the average concentration. The claimed lower limit of the measuring range is 5.0 mg/dl.

For the electrolytes lower limit of linearity, see linearity section above.

e. Analytical specificity:
Interference studies were performed using CLSI EP7-A as a guideline.

Glucose:
Bilirubin (conjugated): No interference found up to 58 mg/dl
Hemolysate: No interference found up to 1000 mg/dl
Lipemia: No interference found up to 1000 mg/dl

Potassium:
Bilirubin (conjugated): No interference found up to 43 mg/dl
Hemolysate: do not use hemolyzed specimens
Lipemia: No interference found up to 1000 mg/dl

Sodium:
Bilirubin (conjugated): No interference found up to 43 mg/dl
Hemolysate: No interference found up to 1000 mg/dl
Lipemia: No interference found up to 1000 mg/dl

Chloride:
Bilirubin (conjugated): No interference found up to 43 mg/dl
Hemolysate: No interference found up to 800 mg/dl
Lipemia: No interference found up to 1000 mg/dl

f. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:
   The method comparison was performed using CLSI (former NCCLS) EP9-A2 as a guideline. The results compared to the Bayer Advia 1650 are presented below.

Analyte	N	Slope	Intercept	R	Sample Range
Gluc(HK)	127	1.00	-1	1.00	11 - 688 mg/dl
ISE Cl	115	0.95	2.8	0.981	80.6 - 165.2 mmol/l
ISE K	121	1.01	-0.1	0.998	2.1 - 9.9 mmol/l
ISE Na	115	0.95	8	0.986	125-196 mmol/l

The results comparing the manual load and the KUSTI sampling systems are presented below.

Analyte	N	Slope	Intercept	R	Sample Range
Gluc(HK)	105	0.99	1.0	1.00	30 - 416 mg/dl
ISE Cl	114	0.98	1.5	0.979	78.9-122.2 mmol/l
ISE K	113	0.98	0.04	0.997	2.7-6.9 mmol/l
ISE Na	113	0.99	0.7	0.989	125-163 mmol/l

b. Matrix comparison:

Protocol (Glucose (HK): Both serum and plasma samples were used in the Method comparison study (DPC T60i vs. Bayer ADVIA (predicate device)). For sample type comparison lithium heparin plasma sample results were analyzed separately.

Protocol (Potassium Micro Volume Electrode): The use of lithium heparin plasma samples was evaluated by a method comparison study with lithium heparin plasma samples measured on a DPC T60i and a Bayer ADVIA (predicate device).

Protocol (Sodium Micro Volume Electrode, Chloride Micro Volume Electrode): The use of lithium heparin plasma samples was evaluated by a comparison study between serum samples and matched lithium heparin plasma samples (samples from Thermo personnel below) and by a comparison study with lithium heparin plasma samples measured on a DPC T60i and a Bayer ADVIA (predicate device)

DPC T60i KUSTI GLUCOSE (HK)

Method comparison study using lithium heparin samples
y = 1.001x - 0.995
r = 1.000
Range 30.8 mg/dl – 416.21 mg/dl
N = 45

DPC T60i KUSTI POTASSIUM MICRO VOLUME ELECTRODE
Method comparison study using lithium heparin samples
y = 0.951x + 0.078
r = 0.992
N = 69

Range 3.44 mmol/l – 6.29 mmol/l

3. Clinical studies:
   a. Clinical Sensitivity:
   Not Applicable
   b. Clinical specificity:
   Not Applicable
   c. Other clinical supportive data (when a. and b. are not applicable):
   Not Applicable
4. Clinical cut-off:
   Not Applicable
5. Expected values/Reference range:
   Expect values are based on literature

N. Instrument Name:

DPC T60i and DPC T60i KUSTI Clinical Chemistry Analyzers

O. System Descriptions:

1. Modes of Operation:
   Random access or batch operation modes are available.
2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes ___X____ or No _____
3. Specimen Identification:
   Bar code, or manually entered
4. Specimen Sampling and Handling:
   Samples can be manually loaded into sample disk for direct sampling from specimen tube or sample cup, or can be automatically routed to KUSTI dispenser to be dispensed in onboard KUSTI segment sample holder. Both methods of sample loading are introduced to the same analytical dispensers.
   - Max On-Board capacity: 6 segments (with 14 positions in each), 6 additional positions for STAT samples.
   - Integrated barcode reader and cup/tube recognition.
   - Optional sample transport interface (KUSTI).
     Sample cups and tubes:
     0.5 ml and 2.0 ml cups, 5 ml and 7 ml tubes, 10 ml tubes with tailored segments.
   - Sample types: Serum, plasma, urine, CSF.
   - Sample volumes: Possible range 1-120 µl ; typically 2-15 µl.
     For Na+, K+ and Cl- tests 50 µl.

   Reagent Tray
   - Reagents are placed into wedge shaped vials On –Board Storage: Continuous
     loading 45 positions in the 4-8 ^{o}C refrigerated reagent compartment.
   - Reagent volumes: 2-250 µl; typically 120 - 200 µl. Up to four reagent

additions / test possible.

5. Calibration:
    - Linear, non-linear or bias calibration.
    - Calibration with separate calibrators or with automatically diluted series from a stock calibrator.
    - Automatically repeated bias correction possibility.
    - 20 positions for calibrator samples in the cooled area of the sample disk. It is also possible to load them into segments.
6. Quality Control:
    - Real time QC with multiple and variable (Westgard) rules.
    - Programmable control interval.
    - 19 positions for control samples in the cooled area of the sample disk.
    - Also possible to load them into segments. QC chart printouts, daily and cumulative reports.
    - Programmable control interval

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Software documentation provided demonstrates the DPC T60i/ DPC T60i Kusti Analyzer was designed and manufactured under well developed software lifecycle processes.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.